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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/635,342      | 08/06/2003  | Nwe Y. BaMaung       | 6958.US.02          | 8084             |

23492 7590 09/29/2004

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EXAMINER

REYES, HECTOR M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/635,342

**Applicant(s)**

BAMAUNG ET AL.

**Examiner**

Hector M Reyes

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/6/03; 1/20/04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**Election**

Applicant's election without traverse of Group I, embracing claims 1-18, in Paper dated August 18, 2004 is acknowledged. Applicant's amendment filed on August 8, 2004 is also amendment.

**Status of the Claims**

Claims 1, 14, 15, and 16 have been amended. Claims 17 and 18 have been canceled. Currently, claims 1-16 are under Examination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaji et al, Bull. Chem. Soc Jpn, 49, pp3181-3184 (1976) or Rich et al, Journal of Org. Chem., 45, pp 2288-2290 (1980).

Kaji discloses 3-amino-2-hydroxy carboxylic acid derivatives embraced by claims 1 and 2, see table 4, page 3183. On the other hand, Rich discloses 3-amino-2-hydroxy-5-methylhexanoic acid, seep age 2289 column II.

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Claims 1, 2, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Craig et al, US patent 6242494. Craig discloses 3-amino-2-hydroxy-5-ethylthio pentanoic acid, see for Example column 26, line 25, second compound.

Claims 1,2, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuda et al, Bull. Chem. Soc. Jpn. 655 (2) pp 360-365 (1992) or Peet et al, J. Med. Chemistry, 33(1) pp 394-407 (1990).

Matsuda discloses a series of 3-amino -2- hydroxy carboxylic acids, see for instance, compounds 2, 4, 13 and compound 13 after step J, corresponding to the methyl ester of compound 13. Likewise, Peet discloses some inhibitors of porcine pancreatic and its synthesis. As part of the said synthetic route, Peet discloses as an intermediate, methyl 3-amino-2-hydroxy butanoate, see compound 19, page 396.

Claims 1,2, 5, 6 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ojima et al, Tetrahedron Letters, 33 (39) pp5537-5700 (1992). Ojima discloses a series of 3-amino-2-hydroxy carboxylates salts and its use as peptide-based inhibitors of various enzymes. See for instance, compounds having general formula 5 and the R1 definition on table 1.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 7-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6242494. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ester compounds in the instant Application overlap with the genus described in claims 1 and 2 of the said patent and the utility of the said compounds is the same as supported in each one of the specifications.

#### **CONCLUSION**

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on Monday to Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Rita Desai can be reached on (571) 272-0684. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Hector M. Reyes PhD JD

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USPTO Reg. # 54846  
AU 1625  
September 24, 2004

A handwritten signature in cursive script, appearing to read "Paul J. Kellogg".

PAUL J. KELLOGG  
PRIMARY EXAMINER